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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,180	DUIJN ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *3-5,8-26 and 30-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,7 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *0102* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *0803* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed December 11, 2002. Currently, claims 1-38 are pending. Claims 3-5, 8-26, 30-38 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election with traverse of Group I (Claims 1-2, 6-7, 27-29) in the Paper filed December 11, 2002 is acknowledged.

The amendment filed December 11, 2002 added Claims 30-38. The response asserts that the new claims are dependent on Claim 1, and are therefore linked. This argument has been thoroughly reviewed, but is not found persuasive because the claims are drawn to patentably distinct inventions. Claims 30-32 are directed to methods, originally restricted to Group II. Claims 33-38 are directed to polypeptides, originally restricted to Group III. Newly submitted claims 30-38 are directed to an invention that is independent or distinct from the invention originally elected for the reasons set forth in the original restriction requirement. Accordingly, claims 30-38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The traversal is on the ground(s) that restriction is only required when the inventions are independent and distinct. This is not found persuasive because dependent inventions may be properly restricted if they are distinct. As discussed in MPEP 803, one of the two criteria for requirement of restriction is that the "inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed".

Accordingly, the demonstration of distinctness of the inventions is sufficient grounds for restriction. As stated in MPEP 802.01 "(t)he law has long been established that dependent inventions (frequently termed related inventions) such as those used for illustration above may be properly divided if they are, in fact "distinct" inventions, even though dependent". Applicants further argue that it would not be an undue burden to examine the claims of all groups I-III. However, it is maintained that undue burden would be required to examine the claims of groups II, III, along with the claims of group I as evidenced by the fact that the claims of groups I, II, III have acquired a separate status in the art as recognized by their different classification and as recognized by their divergent subject matter and because a search of the subject matter of invention 1 is not co-extensive with a search of inventions II-III.

In the event that Claims 1-2, 6-7, 27-29 become directed to an allowable product, pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 30-32, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement would be considered for rejoinder. However, Claims 33-38 are not directed to the process of making or using the patentable product and will not be considered for rejoinder. Furthermore, Claim 3, as written, will not be considered for rejoinder because Claim 3 does not require the nucleic acid of Claim 1.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 3-5, 8-26, 30-38 are drawn to an invention nonelected with traverse. A complete reply to the final rejection must include

cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. This application claims priority to provisional application 60/301,429, filed June 29, 2001.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

While Applicant indicated in the transmittal letter of October 10, 2001 that the instant application claims benefit under 119(e) to 60/301,429, and claimed benefit of these applications under 35 USC 119(e) in the Declaration filed October 10, 2001 and January 23, 2002, Applicant has not requested entry of an amendment to the first line of the specification that identifies the prior nonprovisional applications and indicates the relationship between the instant application and the prior nonprovisional applications. It is noted than an application data sheet has not been filed in the instant application.

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. As provided by United States Patent and Trademark Office OG Notices: 1 March 2003, "The reference required by 37 CFR 1.7 (a)(2) or (a)(5) must be included in

an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title. Previously, the Office indicated that if an applicant includes a benefit claim in the application but not in the manner specified by 37 CFR 1.7 (a) (e.g., if the claim is included in an oath or declaration or the application transmittal letter) within the time period set forth in 37 CFR 1.7 (a), the Office will not require a petition under 37 CFR 1.7 (a) and the surcharge under 37 CFR 1.17(t) to correct the claim if the information concerning the claim was recognized by the Office as shown by its inclusion on the filing receipt."

Moreover, "an incorporation-by-reference statement added after the filing date of an application is not permitted because no new matter can be added to an application after its filing date. See 35 U.S.C. 132(a). If an incorporation-by-reference statement is included in an amendment to the specification to add a benefit claim after the filing date of the application, the amendment would not be proper. When a benefit claim is submitted after the filing of an application, the reference to the prior application cannot include an incorporation-by-reference statement of the prior application. See Dart Industries v. Banner, 636 F.2d 6 4, 207 USPQ 273 (C.A.D.C. 19 0). Therefore, the Office will not grant a petition to accept a benefit claim that includes an incorporation-by-reference statement of a prior application, unless the incorporation-by-reference statement was submitted on filing of the application. Inquiries regarding this notice should be directed to Eugenia A. Jones or Joni Y. Chang, Legal Advisors, Office of Patent Legal Administration, by telephone at (703) 305-1622."

Drawings

4. The transmittal letter, filed October 10, 2001 states that there are "0 sheets of drawings." The instant specification provides a brief description of the drawings (pages 18-19). Therefore, it is unclear whether drawings were intended to be submitted or whether the Brief Description of the Drawings was intended to be omitted. Appropriate correction is required. Applicant is reminded that no new matter may be added.

5. Page 21, line 4 and Page 21, line 22 refers to Figure 1. Page 24, line 20 refers to Figure 2. Page 25 of the specification, line 3, refers to Figure 5, however, the instant specification fails to provide any figures. Additionally, page 26 of the specification refers to Figure 4 in two locations (lines 4 and 18). At page 27, line 1, the specification refers to Fig. 6. Appropriate correction is required.

Sequence Rules

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Specifically, the primers to each of the exons, pages 28-29, do not contain a sequence identifier. Moreover, page 30 contains primers which are not identified by sequence identifier. Appropriate correction is required.

Claim/ Specification Objections

7. Claims 1, 6, 29 are objected to because the claim contains more than one period. For example, SEQ ID NO. 1 contains a period and the end of the claim contains a period. As provided in the MPEP 2422:

> (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

This objection may be easily overcome by amending SEQ ID NO. 1 to read SEQ ID NO: 1 (see MPEP 608.01(m)).

8. Moreover, throughout the specification, SEQ ID NO. 1 is used.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-2, 6-7, 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to "an isolated DNA sequence up to 20 kb in length comprising a nucleic acid sequence as shown in SEQ ID NO: 1." Claim 29 is drawn to a partial sequence of SEQ ID NO: 1.

The phrase "as shown in SEQ ID NO: 1" has been broadly interpreted to mean any sequence shown in SEQ ID NO: 1 embedded within another isolated DNA sequence. For example, the claim encompasses any 10-mer of SEQ ID NO: 1 embedded within another sequence. Alternatively, a claim drawn to an isolated nucleic DNA sequence up to 20 kb in length comprising a nucleic acid sequence of SEQ ID NO: 1 would require a nucleic acid comprising all of SEQ ID NO: 1.

The specification teaches a single isolated DNA sequence within the scope of the claims. The nucleic acid sequence of SEQ ID NO: 1 comprises a single mutation in exon 5, namely a transversion at position 734 in exon 5.

The art teaches a missense mutation converting alanine to aspartic acid at residue 77 (A77D) which was not found in control individuals (Montosi et al. J. of Clinical Investigation, Vol. 108, No. 4, pages 619-623, August 2001). The art also teaches several additional mutations within the ferroportin 1 gene (Devalia et al. Blood, Vol. 100, No. 2, pages 695-697, July 2002). These mutations include a variation in the promoter region of trinucleotide repeats, a G-C transversion within the first intron; a transversion in codon 221, a 3 base pair deletion in exon 5, for example (page 696, col. 1-2).

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from

its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure.

In the instant case, the claims have defined only a fragment of a nucleic acid sequence. Based upon the interpretation of "shown in SEQ ID NO: 1" and "partial sequence" given to the claims, shown in, as stated above, encompasses any nucleic acid sequence "shown in SEQ ID NO: 1" or a "partial sequence of SEQ ID NO: 1" embedded within a larger sequence. In the broadest sense of the interpretation, any nucleic acid comprising an "A" is encompassed by the instant claims, as an "A" is shown in SEQ ID NO: 1. Thus, the claims broadly read upon any number of genes which have not been described in addition to variant SLC11A3 genes not described. The claims broadly encompass nucleic acids which comprise any number of nucleotides of SEQ ID

NO: 1 embedded within larger sequences. For example, the art teaches homo sapiens STS genomic which comprises over 130 nucleotides from SEQ ID NO: 1 (see Olivier, Genbank Accession Number G11389, March 20, 2000). The claims are written broadly enough to genomic and cDNA sequences which have not been described by the instant specification. Thus, the claims broadly encompasses a large genus of nucleic acids which have not been described within the instant specification.

The claims also broadly encompass variant SLC11A3 genes. The art has not described a representative number of SLC11A3 genes. For example, the instant specification fails to describe the missense mutation converting alanine to aspartic acid at residue 77 (A77D) which was not found in control individuals (Montosi et al. J. of Clinical Investigation, Vol. 108, No. 4, pages 619-623, August 2001). The art also teaches several additional mutations within the ferroportin 1 gene (Devalia et al. Blood, Vol. 100, No. 2, pages 695-697, July 2002). These mutations include a variation in the promoter region of trinucleotide repeats, a G-C transversion within the first intron; a transversion in codon 221, a 3 base pair deletion in exon 5, for example (page 696, col. 1-2). Each of these variations are encompassed by the instant claims, however, were not described by the instant specification. The specification has also not defined a structural feature of the variants which would be common to all members of the genus that constitutes a substantial portion of the genus

One of skill in the art would conclude that applicant was not in possession of the claimed "isolated DNA sequences comprising a nucleic acid sequence as shown in SEQ ID NO: 1" or a "partial sequence of SEQ ID NO: 1" because the description of a

single member of this genus is not representative of the variants of the genus and is insufficient to support the claims. Thus, the specification does not adequately provide a written description for "isolated DNA sequences comprising a nucleic acid sequence as shown in SEQ ID NO: 1" or a "partial sequence of SEQ ID NO: 1."

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 6-7, 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 6-7 are indefinite over the recitation "a sequence unique to SEQ ID NO: 1" because it is unclear what constitutes a sequence unique to SEQ ID NO: 1. Based upon the disclosure in the specification and the art, the art teaches SEQ ID NO: 1 with a single base pair transversion at position 734. Moreover, the art teaches numerous primers or oligonucleotides, including every possible 10-mer oligonucleotide. Therefore, it is unclear what constitutes a unique sequence. It is unclear whether the oligonucleotide must be unique in compared to the "wild-type" sequence or whether the oligonucleotide is unique over all nucleic acids, in which case, the only unique SEQ ID NO: 1 would appear to be itself. Furthermore, it is unclear whether the at least 8 nucleotides must be from a sequence unique to SEQ ID NO: 1, but need not be unique themselves. For example, SEQ ID NO: 1 is unique to SEQ ID NO: 1, therefore, it is unclear whether any 8 consecutive nucleotides from SEQ ID NO: 1 would fall within the

scope of the claims. Thus, the metes and bounds of " a sequence unique to SEQ ID NO: 1" is unclear.

B) Claims 27-28 are indefinite over the recitation (A734C) because it is unclear whether this parenthetical further limits the claim or whether the parenthetical is merely providing an example of a polymorphism at position 734.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-2, 6-7, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by McKie et al. (Genbank Accession Number AF231121, March 2000).

McKie teaches the IREG1 complete cDNA comprising over 1,500 contiguous nucleotides from SEQ ID NO: 1 (limitations of Claim 2). The nucleic acid of SEQ ID NO: 1 and McKie differ only at a single nucleotide, namely nucleotide 734. The nucleic acid of McKie is an isolated DNA sequence up to 20 kb in length comprising a nucleic acid shown in SEQ ID NO: 1. The nucleic acid shown in SEQ ID NO: 1 is nucleotides 735-2243 of McKie (limitations of Claim 1).

With respect to Claim 6-7, the nucleic acid is at least 8 consecutive nucleotides selected from SEQ ID NO: 1, namely nucleotides 1-733 are 100% identical. Claim 7 remains drawn to a single oligonucleotide. The limitations of Claim 7 do not add any

structural limitations to the Claims, therefore, the nucleic acid of McKie anticipates the claim.

With respect to Claim 29, McKie teaches a nucleic acid comprising a partial sequence of SEQ ID NO: 1, namely positions 735-2243. The nucleic acids of McKie may be used as a predictive marker for HH gene mutation. If the "normal" DNA hybridizes under high stringent conditions, this may be used to indicate that no mutation is present. Moreover, the normal may be used in sequencing assays to predict that there is no HH gene mutation.

12. Claims 1, 6-7, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Olivier et al. (Genbank Accession Number G11389, March 2000).

Olivier et al. (herein referred to as Olivier) teaches a nucleic acid from human STS genomic sequence tagged site. The nucleic acid comprises over 130 contiguous nucleotides from the complement of SEQ ID NO: 1 (limitations of Claim 1). Positions 2036-2062 of SEQ ID NO :1 is 100% identical to positions 286-153 of Olivier. Olivier also teaches two primers, namely primer A and primer B which are located within SEQ ID NO: 1. These nucleic acids are 20 nucleotides in length. Therefore, each of these primers are at least 8 consecutive nucleotides from SEQ ID NO: 1 which are part of an oligonucleotide pair for amplification (limitations of Claim 6-7).

With respect to Claim 29, the two primers, namely primer A and primer B comprise a partial sequence of SEQ ID NO: 1. These oligonucleotides would have the property of amplifying the gene, thus would be predictive of a HH gene mutation.

13. Claims 1-2, 6-7, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796, December 12, 1995).

The instant claims are drawn to an isolated DNA sequence comprising a nucleic acid shown in SEQ ID NO: 1. Shown in has been broadly interpreted to mean any fragment which is depicted in SEQ ID NO: 1. Thus, fragments of 10 nucleotides is encompassed within the claims. .

Furthermore, "unique" has been broadly interpreted to mean any sequence which appears in SEQ ID NO: 1 for the reason provided in the 112/2nd rejection above.

Brennan teaches oligonucleotides having 10 nucleotides each (10-mers). The oligonucleotides represent every possible permutation of the 10-mer oligonucleotide. Therefore, Brennan teaches every possible 10-mer nucleic acid. The 10-mer oligonucleotides taught by Brennan represent every possible nucleic acid fragment from within SEQ ID NO: 1.

With respect to Claim 2, the 10-mer nucleic acids synthesized by Brennan are DNA molecules. CDNA molecules are composed of DNA nucleotides, just as DNA molecules are composed of DNA nucleotides. The structure of cDNA is the same as DNA molecules. Thus, the same sequence is chemically identical. Therefore the 10-mer molecules of Brennan do not differ in structure from 10-mer cDNA molecules.

With respect to Claim 29, the 10-mer nucleic acids of Brennan comprise a partial sequence of SEQ ID NO: 1. The oligonucleotides would minimally have the property of amplifying the gene, thus would be predictive of a HH gene mutation.

14. Claims 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim (1997 Biochemicals Catalog, page 95).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02).

Boehringer Mannheim teaches a kit comprising hybridization bags which can be used in non-radioactive hybridization and detection procedures. This is a kit as minimally required by Claim 27. Moreover, the kit can be used for detecting the presence or absence of a base mutation in a hybridization or detection procedure.

Also, Boehringer Mannheim teaches a hexanucleotide mix provided within a kit. The mixture of hexamer nucleotides comprises primers for amplifying DNA containing the base-pair polymorphism. Thus, the Boehringer Mannheim Catalog teaches a kit comprising primers for amplifying the DNA containing the base-pair polymorphism at position 734 of the SLC11A3 gene.

Allowable Subject Matter

15. An isolated nucleic acid of SEQ ID NO: 1 is free of the art. The art does not teach cDNA from the SLC11A3 (SEQ ID NO: 1) containing a mutation in exon 5, position 734 which results in a transversion between an A-C. The instant specification states that "all symptomatic HH patients contain a heterozygous A-to-C transversion at

position 734 (A734C) compared to 200 healthy controls (page 25, para 63). The specification states that the base change is the causative mutation for HH.

Conclusion

16. No claims allowable over the art.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
Patent Examiner
August 7, 2003